

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV724615776US  
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August 11, 2005  
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF  
MENART ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP2003/006134

FILED: 11 JUNE 2003

U.S. APPLICATION NO: 10/522,826

35 USC §371 DATE: 21 JULY 2005

FOR: PROCESS FOR THE PRODUCTION OF INCREASED AMOUNTS  
OF CORRECTLY FOLDED HETEROLOGOUS PROTEIN IN  
INCLUSION BODIES

**MS: PCT**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

COMMUNICATION IN RESPONSE TO THE  
NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. § 371

Sir:


On July 25, 2005, the USPTO issued the Notification of Missing Requirements Under 35 U.S.C. § 371, a copy of which is enclosed.

This Notification of Missing Requirements was not necessary as the undersigned submitted the executed Declaration to the USPTO on July 21, 2005 in a Second or Subsequent Submission of Items Concerning a Filing Under 35 U.S.C. § 371. Enclosed please find a copy this Second or Subsequent Submission, a copy of the executed Declaration, and a copy of the date stamped postcard from the USPTO acknowledging receipt by the PCT/PTO on July 21, 2005, prior to the mail date of the Notification of Missing Requirements.

Because Applicants submitted the executed Declaration prior to the issuance of the Notification of Missing Requirements, no fee is required.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(862) 778-7945  
Date: 8/11/05

  
John D. Thallemer  
Attorney for Applicants  
Reg. No. 34,940

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## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
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 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/522,826	Viktor Menart	LB/G-32991A/LEK

1095  
 NOVARTIS  
 CORPORATE INTELLECTUAL PROPERTY  
 ONE HEALTH PLAZA 104/3  
 EAST HANOVER, NJ 07936-1080

INTERNATIONAL APPLICATION NO.	
PCT/EP03/06134	
LA. FILING DATE	PRIORITY DATE
06/11/2003	07/31/2002

CONFIRMATION NO. 4902  
 371 FORMALITIES LETTER



\*OC000000016580447\*

Date Mailed: 07/25/2005

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 01/31/2005
- Copy of the International Search Report filed on 01/31/2005
- Copy of IPE Report filed on 01/31/2005
- Preliminary Amendments filed on 01/31/2005
- Information Disclosure Statements filed on 01/31/2005
- U.S. Basic National Fees filed on 01/31/2005
- Priority Documents filed on 01/31/2005



The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

## SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Late oath or declaration Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

DOCKETED

Sept. 25, 2005

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The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

DEBORAH D WILLIAMS

Telephone: (703) 308-9140 EXT 205

**PART 2 - OFFICE COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/522,826	PCT/EP03/06134	LB/G-32991A/LEK

FORM PCT/DO/EO/905 (371 Formalities Notice)

EV 72461564305  
Express Mail Label Number

July 21, 2005  
Date of Deposit

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Form PTO-1390-MOD (REV 10-96)		U. S. Department of Commerce Patent and Trademark Office	ATTORNEY'S DOCKET NUMBER LB/G-32991A
<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371</b>			U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/522,826
INTERNATIONAL APPLICATION NO. PCT/EP2003/006134	INTERNATIONAL FILING DATE 11 June 2003 (11.06.03)	PRIORITY DATE CLAIMED 31 July 2002 (31.07.02)	
TITLE OF INVENTION PROCESS FOR THE PRODUCTION OF INCREASED AMOUNTS OF CORRECTLY FOLDED HETEROLOGOUS PROTEIN IN INCLUSION BODIES			
APPLICANT(S) FOR DO/EO/US MENART ET AL.			

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau. (See Form PCT/IB/308)
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An executed Declaration and Power of Attorney (original or copy) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included.

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.  
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the International application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information:

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)  
**10/522,826**

INTERNATIONAL APPLICATION NO.  
**PCT/EP2003/006134**

ATTORNEY'S DOCKET NUMBER  
**LB/G-32991A**

The following fees are submitted:

21. Basic national fee. ....	\$
22. Examination Fee	
If International preliminary examination report was prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) .....	\$
All other situations. ....	\$
23. Search fee	
If Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority. ....	\$
If International Search Report was prepared and provided to the Office. ...	\$
All other situations. ....	\$

**CALCULATIONS** PTO USE ONLY

**TOTAL OF 21, 22 AND 23 =**

**\$ 0**

Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.

Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE
- 100 =	/50 =		X \$ 250

Surcharge of \$130 for furnishing the oath of declaration later than ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).

**\$ 130**

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	- 20 =		X \$ 50
Independent claims	- 3 =		X \$ 200
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$ 360

**TOTAL OF ABOVE CALCULATIONS =**

**\$ 130**

Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).

**SUBTOTAL =**

**\$ 130**

Processing fee of \$130 for furnishing the English translation later than ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).

**TOTAL NATIONAL FEE =**

**\$ 130**

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property

**TOTAL FEES ENCLOSED =**

**\$ 130**

Amount to be: refunded	\$
charged	\$

- a. ☐ A check in the amount of \$\_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of \$130 to cover the above fees. A duplicate copy of this form is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134 in the name of Novartis.

**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to the address associated with Customer No. 001095, which is currently:

Novartis  
 Corporate Intellectual Property  
 One Health Plaza, Building 104  
 East Hanover, NJ 07936-1080

*John D. Thallemer*  
 John D. Thallemer  
 Attorney for Applicants  
 Reg. No. 34,940  
 (862) 778-7945

**BEST AVAILABLE COPY****DECLARATION AND POWER OF ATTORNEY FOR UNITED STATES PATENT APPLICATION**☒ Original☐ Supplemental☐ Substitute

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, and

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if more than one name is listed below) of the subject matter which is claimed and for which a United States patent is sought on the invention entitled

**PROCESS FOR THE PRODUCTION OF INCREASED AMOUNTS OF CORRECTLY FOLDED HETEROLOGOUS PROTEIN IN INCLUSION BODIES**

the specification of which:

☐ is attached hereto.

☐ was filed on \_\_\_\_\_ as Application No. \_\_\_\_\_  
(day/month/year)

and, if this box (☐) contains an \*

☐ was amended on \_\_\_\_\_  
(day/month/year)

☒ was filed as Patent Cooperation Treaty international Application No.

PCT/EP2003/006134 on 11/06/2003  
(day/month/year)

and, if this box (☐) contains an \*

☐ entered the national stage in the United States and was accorded Application No. \_\_\_\_\_

and, if this box (☐) contains an \*

☐ was amended, subsequent to entry into the national stage, on \_\_\_\_\_  
(day/month/year)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) specifically referred to above and, if this application was filed as a Patent Cooperation Treaty international application, by any amendments made during the international stage (including any made under Patent Cooperation Treaty Rule 91, Article 19 and Article 34).

I acknowledge my duty to disclose information which is material to patentability as defined in 37 C.F.R. 1.56, including, for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or Patent Cooperation Treaty international filing date of the continuation-in-part application.

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I hereby claim the benefit under 35 U.S.C. 119(a)-(d) or (f) or 365(b) of any foreign application(s) for patent, inventor's certificate or plant breeder's right certificate listed below and under 35 U.S.C. 365(a) of any Patent Cooperation Treaty international application(s) designating at least one country other than the United States listed below and have also listed below any foreign application(s) for patent, inventor's certificate or plant breeder's right certificate and Patent Cooperation Treaty international application(s) designating at least one country other than the United States for the same subject matter and having a filing date before that of the application the priority of which is claimed for that subject matter:

COUNTRY/REGION (OR P.C.T.)	APPLICATION No.	FILING DATE (day/month/year)	PRIORITY CLAIMED	
Slovenia	P200200187	31/07/2002	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below:

APPLICATION NO.	FILING DATE (day/month/year)
-----------------	---------------------------------

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s) listed below and under 35 U.S.C. 365(c) of any Patent Cooperation Treaty international application(s) designating the United States listed below:

United States Application No.	United States Filing Date (day/month/year)	Status (Pending, Abandoned or U.S. Patent No.)	International Application No. and Filing Date (day/month/year)
----------------------------------	--	--	--

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I hereby appoint all of the registered practitioners associated with Customer No. 001095, respectively and individually, as my attorneys and agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

If this box (☐) contains an x ☒, I hereby authorize the registered practitioners associated with Customer No. 001095 and any others acting on my behalf to take any action relating to this application based on communications from Corporate Intellectual Property of Novartis International AG, Basle, Switzerland, or an affiliate thereof or a successor thereto, without direct communication from me.

Please send all correspondence relating to this application to the address associated with Customer No. 001095.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

---

Full name of sole  
or first joint inventor

**Viktor MENART**

Inventor's signature



Date

4. Jan. 2005  
(day/month/year)

Residence

**1370 Logatec, Slovenia**

Citizenship

**citizen of Slovenia**

Post Office Address

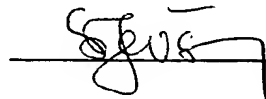
**Dol 3  
1370 Logatec  
Slovenia**

---

Full name of second  
joint inventor, if any

**Simona JEVSEVAR**

Inventor's signature



Date

4. Jan. 2005  
(day/month/year)

Residence

**2000 Maribor, Slovenia**

Citizenship

**citizen of Slovenia**

Post Office Address

**Vodole 26  
2000 Maribor  
Slovenia**

---

**IMPORTANT:** Before this declaration is signed, the patent application (the specification, the claims and this declaration) must be read and understood by each person signing it, and no changes may be made in the application after this declaration has been signed.



**BEST AVAILABLE COPY**Full name of third  
joint inventor, if any**Vladka GABERC POREKAR**

Inventor's signature

*J. Porekar*

Date

*4 January 2005*

(day/month/year)

Residence

**1000 Ljubljana, Slovenia**

Citizenship

**citizen of Slovenia**

Post Office Address

**Vrhovci c. X/43  
1000 Ljubljana  
Slovenia**Full name of fourth  
joint inventor, if any

Inventor's signature

Date

(day/month/year)

Residence

Citizenship

Post Office Address

Full name of fifth  
joint inventor, if any

Inventor's signature

Date

(day/month/year)

Residence

Citizenship

Post Office Address

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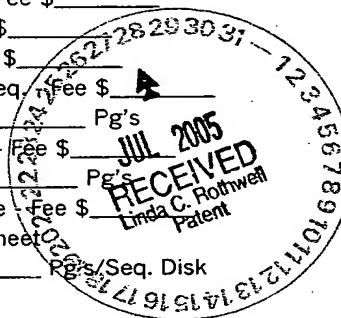
Case No. LB/G-32991A/LEK.  
Application No. 101522,826  
Mailing Date: July 21, 2005  
Due Date: \_\_\_\_\_  
Express Mail No.: EV72461564305

The Patent & Trademark Office acknowledges, and has stamped hereon the date of receipt of the items checked below:

- ☐ Amendment/Response/Letter - Fee \$ \_\_\_\_\_  
☐ Appln. Filing Papers - Fee \$ \_\_\_\_\_  
☐ PCT National Stage  
☐ Provisional Application  
☐ RCE ☐ DIV ☐ CONT ☐ CIP  
☐ Specification \_\_\_\_\_ Pg's  
☒ Executed/Unexecuted Decl. - Fee \$ 30.00  
☐ Missing Parts/Missing Req.  
☐ Preliminary Amendment \_\_\_\_\_ Pg's  
☐ Claim of Priority ☐ Certified Copy(s)  
☐ Amendment After Final  
☐ Notice of Appeal - Fee \$ \_\_\_\_\_  
☐ Appeal Brief - Fee \$ \_\_\_\_\_  
☐ Issue Fee Payment \$ \_\_\_\_\_  
☐ Assignment Rec. Req. Fee \$ \_\_\_\_\_  
☐ Formal Drawings \_\_\_\_\_ Pg's  
☐ IDS \_\_\_\_\_ Pg's - Fee \$ \_\_\_\_\_  
☐ PTO-1449 Form \_\_\_\_\_ Pg's  
☐ Pet. for Ext. of Time - Fee \$ \_\_\_\_\_  
☐ Application Data Sheet \_\_\_\_\_  
☐ Seq. Listings \_\_\_\_\_ Pg's/Seq. Disk  
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Initials

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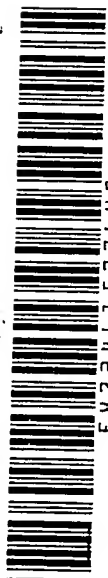
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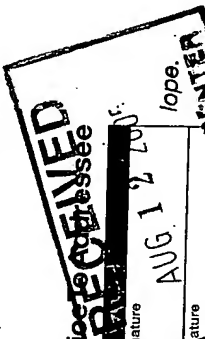
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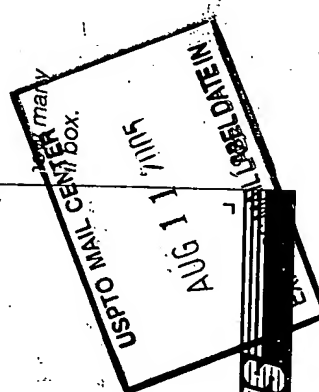
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